K102885

JAN 14 2011

510(k) Summary of Safety and Effectiveness:

Hoffmann II External Fixation Line Extension

Proprietary Name:	Hoffmann II External Fixation System Line Extension
Common Name:	External Fixation System
Classification Name and Reference:	Single Multiple component metallic bone fixation appliance and accessories, 21 CFR §888.3030 and Smooth or Threaded Metallic Fixation Fastener 21 CFR §888.3040
Regulatory Class:	Class II
Product Codes:	87LXT: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Components Metal Composite 87JEC: Component, Traction, Invasive
For Information contact:	Zamir Bar-David Regulatory Affairs consultant Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 (201) 831-6455 (Phone) (201) 831-3365 (Fax) zamir.bardavid@stryker.com
510(k) Alternate Contact Person:	Avital Merl-Margulies Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 (201) 831-6365 (Phone) (201) 831-3365(Fax) avital.merl.margulies@stryker.com (e-mail)
Date Prepared:	September 29, 2010

K102885

Description:
The Hoffmann II External Fixation System originally cleared under K952730, K971755, K003211 and K031941 includes clamps, couplings and rods used in conjunction with half pins or transfixing pins of the Hoffmann External Fixation System cleared under K861766 and is intended to be used for the stabilization of fractures of the tibia, femur, humerus, radius or pelvis.

Intended Use:
Hoffmann II External Fixation System consists of a system of clamps, couplings and used to provide stabilization of open and/or unstable fractures of the tibia, femur, humerus, radius or pelvis, and where soft tissue injury may preclude the use of other fracture treatments such as IM rods, casts, or other means of internal fixation.

Indications:
The Hoffmann II External Fixation System is intended to be used in the stabilization of open and/or unstable fractures and where the soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting and other means of internal fixation.

The indications for use of metallic external fixation devices include:

- Bone fracture fixation
- Osteotomy
- Arthrodesis
- Correction of deformity
- Revision procedures where other treatments or devices have been unsuccessful
- Bone reconstruction procedures

Proposed Modification:
This special 510(k) submission is intended to provide an alternate stainless steel material (Biodur 108) to manufacture Hoffmann II coupling components. Currently the subject Hoffmann II components are manufactured from stainless steel, Custom 455.

Summary of Data:
Analysis and testing of the alternate material used on the Hoffmann II External Fixation demonstrated equivalent stability and performance compared to its predicate device. This was done by analyzing different combinations of the subject Hoffmann II External Fixation Line extension components made of Custom 455 with components of Hoffmann II MRI System made from the proposed Biodur material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp
% Mr. Zamir Bar-David
325 Corporate Drive
Mahwah, New Jersey 07430

JAN 14 2011

Re: K102885
Trade/Device Name: Hoffmann II External Fixation System Line Extension
Regulation Number: 21 CFR 888.3040
Regulation Name: Single multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: JEC, LXT
Dated: December 20, 2010
Received: December 21, 2010

Dear Mr. Bar-David:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102885

Device Name: Hoffmann II External Fixation System Line Extension

Indications for Use:

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- Revision procedures where other treatments or devices have been unsuccessful
- Bone reconstruction procedures

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102885